Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1994

DOW CORNING CORPORATION,

Petitioner,

v.

MARIANN HOPKINS,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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78

QUESTIONS PRESENTED

1. May a federal appellate court after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ___, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) uphold admission of expert scientific testimony when the district court refused to make any preliminary assessment of its scientific reliability and the proffered testimony met none of *Daubert's* reliability criteria?

2. In a diversity case, may a federal appellate court sustain a jury's punitive damage award, attacked on due process grounds, by adding standards to constrain discretion of California factfinders and of the district court that exist neither in California law nor federal law without violating the rules of *Erie R.R. Co. v. Tompkins* and *Browning-Ferris Indus. of Vermont v. Kelco Disposal, Inc.*, and impairing procedural due process guaranteed by the Fifth Amendment?

PARTIES

The parties are Dow Corning Corporation[1] and Mariann Hopkins.

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[1] Pursuant to Rule 29.1, petitioner states that Dow Corning Corporation is wholly owned by The Dow Chemical Corporation and by Corning Incorporated. The Dow Chemical Corporation's non-wholly-owned subsidiaries whose stock is publicly traded are Destec Energy, Inc., and Marion Merrell Dow, Inc. Corning Incorporated's non-wholly-owned subsidiaries are Calp, Iwaki Glass, Unilab Corp., Owens Corning.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES ii

OPINION 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS 1

STATEMENT OF THE CASE 2

REASONS FOR GRANTING THE WRIT 12

A. *The National Importance of the Admissibility of Proffered Expert Scientific Testimony* 12

B. *The National Importance of the Standards of Judicial Review of Punitive Damages in Diversity Cases* ... 16

C. *The Ninth Circuit's Interpretation of Daubert Conflicts with the Opinions of Other Circuits* 18

D. *The Ninth Circuit Violated Browning-Ferris and Impaired Petitioner's Procedural Due Process Rights by Adding Standards to Constrain Discretion in Awarding Punitive Damages that do not exist in California or Federal Law* 21

E. *The Circuits are in Conflict on the Application of Haslip to Punitive Damage Awards in Diversity Cases* 25

CONCLUSION 28

APPENDIX A – Opinion ..... App. 1

APPENDIX B – Order Denying New Trial ..... App. 32

APPENDIX C – Judgment ..... App. 40

APPENDIX D – Order Denying Rehearing ..... App. 42

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Allied Chemical Corp. v. Daiflon, Inc., 449 U.S. 33, 66 L. Ed. 2d 193, 101 S. Ct. 188 (1980) 23

Auster Oil & Gas, Inc. v. Stream, 835 F.2d 597 (5th Cir. 1988) 24

Bankers Life & Casualty Co. v. Crenshaw, 486 U.S. 71, 108 S. Ct. 1645, 100 L. Ed. 2d 62 (1988) 23

Bonn v. Puerto Rico Int'l Airlines, Inc., 518 F.2d 89 (1st Cir. 1975) 24

Bourjaily v. United States, 483 U.S. 171, 99 F.2d 144, 107 S. Ct. 2775 (1987) 11

Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 1511 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046, 108 L. Ed. 2d 646 110 S. Ct. 1511 (1990) 21

Browning-Ferris Indus. v. Kelco Disposal, Inc., 492 U.S. 257, 106 L. Ed. 2d 219, 109 S. Ct. 2909 (1989) 17, 21, 23, 25, 26

Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 100 S. Ct. 2548 (1986) 20

Community Television Services, Inc. v. Dresser Industries, Inc., 435 F. Supp. 214 (D.S.D. 1977), *aff'd*, 586 F.2d 637 (8th Cir. 1978) 24

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. ___, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) ..... *passim*

Elkins v. Richardson-Merrell, Inc., 8 F.3d 1068 (6th Cir. 1993) 19

TABLE OF AUTHORITIES – Continued

Page

Erie R.R. Co. v. Tompkins, 304 U.S. 64, 58 S. Ct. 817, 82 L. Ed. 1188 (1938) 26

Fairmount Glass Works v. Cub Fork Coal Co., 287 U.S. 474, 77 L. Ed. 439, 53 S. Ct. 252 (1933) 23

Gertz v. Robert Welch, Inc., 418 U.S. 323, 41 L. Ed. 2d 789, 94 S. Ct. 2997 (1974) 22

Honda Motor Co., Ltd. v. Oberg, ___ U.S. ___, 129 L. Ed. 2d 336, 114 S. Ct. 2331 [62 U.S.L.W. 4627] (1994) 16, 18, 25

Hopkins v. Dow Corning Corp., 33 F.3d 1116 (1994) 1

In Re Joint E. & S. Dist. Asbestos Litig., 129 B.R. 710 (E & S D.N.Y. 1991), *vacated on other grounds*, 982 F.2d 721 (2d Cir. 1992) 16

Latham Seed Co. v. Nickerson American Plant Breeders, Inc., 978 F.2d 1493 (8th Cir. 1992) 27

Mattison v. Dallas Carrier Corp., 947 F.2d 95 (4th Cir. 1991) 25

Mekdeci v. Merrill National Lab., 711 F.2d 1510 (11th Cir. 1983) 14

Nairn v. National R.R. Passenger Corp., 837 F.2d 565 (2d Cir. 1988) 24

O'Conner v. Commonwealth Edison Co., 13 F.3d 1090 (7th Cir. 1994) 19

Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 113 L. Ed. 2d 1, 111 S. Ct. 1032 (1991) 9, 22, 24, 25, 27

Porter v. Whitehall Laboratories, Inc., 9 F.3d 607 (7th Cir. 1993) 20

TABLE OF AUTHORITIES – Continued

Page

Sorenson v. Shaklee Corp., 31 F.3d 638 (8th Cir. 1994) 20

Superbird Farms, Inc. v. Perdue Farms, Inc., 970 F.2d 238 (7th Cir. 1992) 24

Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ___, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992) 21

United States v. Bonds, 12 F.3d 540 (6th Cir. 1993) 21

United States v. Martinez, 3 F.3d 1191 (8th Cir. 1993) 21

United States v. Rincon, 11 F.3d 922 (9th Cir. 1993) (second opinion after remand.) 14

United States v. Rincon, 984 F.2d 1003 (9th Cir.), *vacated and remanded for further consideration in the light of Daubert*, ___ U.S. ___, 126 L. Ed. 2d 12, 114 S. Ct. 41 (1993) 14

Wheat v. Pfizer, Inc., 31 F.3d 340 (5th Cir. 1994) 19

Whitely v. OKC Corp., 719 F.2d 1051 (10th Cir. 1983) 24

STATE CASES

Adams v. Murakami, 54 Cal.3d 105, 284 Cal.Rptr. 318 (1991) 22

Neal v. Farmers Ins. Exchange, 21 Cal.3d 910, 148 Cal.Rptr. 389 (1978) 23

FEDERAL STATUTES

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1332 1

TABLE OF AUTHORITIES – Continued

Page

Federal Rules of Civil Procedure, Rule 50(b) 26

Federal Rules of Civil Procedure, Rule 59 ..... 1, 17, 23, 26, 27

Federal Rules of Evidence, Rule 104(a) 1, 10, 11, 18

TREATISES AND LAW REVIEW ARTICLES

California Approved Jury Instructions: Civil No. 14.72.2 (rev. ed. 1989) 8

GAO Briefing Report to the Chairman, Subcommittee on Commerce, Consumer Protection and Competitiveness, Committee on Energy and Commerce, House of Representatives: Products Liability Extent of "Litigation Explosion" in Federal Courts Questioned, 2-3, 20-28 (1988) 16

J.B. Weinstein, "Ethical Dilemmas in Mass Tort Litigation," 88 *Nw. U.L. Rev.* 469 (1994) 13

J. Sanders, "The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts," 43 *Hastings L.J.* 301 (1992) 13

L. Brickman, "On the Relevance of the Admissibility of Scientific Evidence: Tort System Outcomes are Principally determined by Lawyers' Rates of Return," 15 *Cardozo L. Rev.* 1755 (1994) 13

P. Huber, "Safety and the Second Best: The Hazards of Public Risk Management in the Courts," 85 *Colum. L. Rev.* 277 (1985) 13

S. Sugarman, "Doing Away with Tort Law," 73 *Calif. L. Rev.* 555 (1985) 13

OPINION

The opinion of the United States Court of Appeals for the Ninth Circuit is reported in 33 F.3d 1116 (1994). A copy of the slip opinion is annexed hereto as Appendix A ("App. 1").

JURISDICTION

The opinion of the court of appeals was filed on August 26, 1994. A timely petition for rehearing and suggestion for *en banc* consideration was denied on October 11, 1994. App. 42. (Appendix D). Jurisdiction of the district court was based on diversity of citizenship. 28 U.S.C. § 1332. Jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

The Fifth Amendment to the United States Constitution provides, in pertinent part: "No person shall . . . be deprived of . . . property, without due process of law. . . . "

The applicable portions of Rule 104(a) of the Federal Rules of Evidence and Rule 59 of the Federal Rules of Civil Procedure are set forth in footnotes to the text hereof.

STATEMENT OF THE CASE

Pretrial. Respondent filed her personal injury action in the federal district court, invoking diversity jurisdiction, in December, 1988. She alleged that her rare autoimmune disease (mixed connective tissue disease "MCTD"), definitely diagnosed in 1979, was caused by prescription mammary prostheses manufactured by petitioner and first implanted in her by Dr. Karl Bollinger in 1976 to reconstruct her breasts after a bilateral mastectomy. ER 1.[2]

Petitioner moved for summary judgment on the grounds that the respondent's evidence of a causal connection between her prostheses and her disease was insufficient to create a triable issue of fact and that her personal injury claim was barred by the applicable California's one-year statute of limitations. The motion was denied. After extensive discovery, petitioner filed a motion *in limine* to exclude the testimony of respondent's three designated expert causation witnesses, Drs. Marc Lappé, Nir Kossovsky and Frank Vasey, because none of their opinions was scientifically reliable or based on a methodology or technique accepted by any relevant scientific community.

The evidence before the district court in ruling on the pre-trial motion revealed the following uncontroverted facts:

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[2] Throughout this Petition, the following abbreviations are used: "ER" (Excerpts of the Record filed with the Ninth Circuit); "RT" (Reporter's Transcripts), and "App." refers to the Appendix attached hereto.

In mid-1975, respondent had a number of symptoms that were consistent with early signs of MCTD. Dr. Pelfini, her internist, ordered a test for autoimmune disease that proved inconclusive. In October, 1976, Dr. Karl Bollinger performed a bilateral subcutaneous mastectomy on respondent and, as part of the same surgery, reconstructed her breasts by using two prescription gel-filled silicone mammary prostheses manufactured by petitioner. In 1977, Dr. Bollinger replaced those prostheses with a second set, also manufactured by petitioner, due to post-surgical complications unrelated to the prostheses. When in 1979 respondent continued to suffer from the symptoms that Dr. Pelfini recorded in 1975, he referred her to Dr. Gospe, a rheumatological specialist, who ordered another autoimmune disease test. That test was positive. Dr. Gospe's medical records state that respondent's MCTD had begun between 2½ to 3 years before he saw her. Dr. Gospe continued to treat her for her rheumatological disorder for the next 10 years.

In 1985, after petitioner had received some case reports hypothesizing immunological sensitivity to gel-filled prostheses, it rewrote its package inserts accompanying the prostheses shipped to prescribing physicians. To earlier described possible adverse effects, the new insert added: "There have been reports of suspected immunological sensitization or hyperimmune response to silicone mammary implants. . . . [C]laims from clinical use of silicone prostheses in humans suggests that immunological responses or sensitization in mammary prosthesis can occur. . . . " ER CC. Physicians were warned to remove the prostheses if sensitization was suspected. *Ibid.*

Because her prostheses were sagging, respondent consulted Dr. Bollinger in January, 1986, and she thereupon decided to have her second set of implants replaced. Although Dr. Bollinger had read petitioner's package inserts and he knew that she was suffering from MCTD, he told petitioner nothing about petitioner's warning of possible immunological sensitivity to gel-filled prostheses. When Dr. Bollinger undertook replacement surgery on February 20, 1986, he discovered that her second set of implants had ruptured. Until then, he and the respondent had assumed that the replacement would be a simple procedure under local anesthetic. He immediately told respondent what he had discovered and explained to her that removal of the damaged prostheses would require lengthy surgery under general anesthetic. After she was generally anesthetized, he removed the prostheses and replaced them with her third set of prostheses manufactured by petitioner.

Shortly after that surgery, Dr. Bollinger told respondent that the prostheses had been returned to petitioner for analysis by its laboratory and that he would thereafter receive a laboratory report. Respondent asked to read the report when he received it. She thereafter read the report which described the methodology of the analysis and concluded with the opinion that the analysis revealed "no evidence to indicate that any damage was manufacture [sic] related." ER DD.

Although her third set of implants had not failed, she was dissatisfied with her appearance and transferred her care from Dr. Bollinger to Dr. Tavis. Dr. Tavis explanted her third set and implanted her fourth set of petitioner's prostheses in late 1986. In 1991, she had her fourth set

removed by Dr. Shaw, who performed a bilateral reconstruction from her own tissue. ER B.

None of her medical records stated any cause of her MCTD or hypothesize any connection between her disease and her prostheses.

Dr. Lappé has a Ph.D degree in experimental pathology. He is not a chemist, an immunologist, an epidemiologist, or a toxicologist, and he is not qualified to diagnose or treat human beings. His experimental pathology research involved animal studies, none of which was recent, and his own research had not included an investigation of silicone products. His opinion was based on his examining 226 laboratory studies out of 869 laboratory studies produced by petitioner during discovery. These were tests of the safety of silicone and silicone products used in manufacturing mammary prostheses; they were performed by petitioner's laboratory and outside laboratories. Although none of the researchers who performed those studies found relevant adverse effects on immune systems, Dr. Lappé disagreed. He testified that respondent's 1976 and 1977 prostheses "could have contributed to the reaction but was not a primary cause of this reaction"; he said that a causal link between the two is "an open question in the strict scientific sense of establishing causality."

Dr. Kossovsky's deposition revealed that he is an experimental pathologist, not an immunological pathologist, rheumatologist, a chemist, or an epidemiologist. His opinion was based on one study that he had conducted in which he had injected guinea pigs with a combination of silicone and animal protein in which he observed an

immunological reaction in the animals, and his review of some slides of respondent's tissue in which he believed he saw evidence of bioreactivity. He conceded that the results of animal studies cannot be readily extrapolated to human beings. Dr. Kossovsky testified that there is "no direct evidence of a causal connection between the two [autoimmune disease and breast prostheses], but that is one of the chronic problems in making a medical diagnosis."

Dr. Vasey's deposition revealed that he is an academic rheumatologist and that he is not qualified in any other relevant scientific field. His opinion was based on his own clinical observations of some of his patients. He said that the risk of some connection between silicone and MCTD was not quantifiable.

In denying petitioner's motions for summary judgment and to exclude the testimony of respondent's causation experts, the district court declined to make any Rule 104(a) preliminary assessment of the scientific reliability of the proffered testimony. The court expressed the view that the question of scientific reliability of the expert witnesses' testimony would be left to the jury.

Trial. After overruling petitioner's repeated objections to the testimony of respondent's expert causation witnesses based on the lack of any scientific foundation for their testimony, Drs. Lappé, Kossovsky and Vasey testified extensively at trial. Although their confidence in their opinions had increased since their depositions were taken, the foundation for their testimony was unchanged.

During the trial, the testimony of Drs. Kossovsky and Vasey and the testimony of petitioner's highly qualified

expert scientific witnesses agreed on one point: The cause of MCTD is not known. All that is scientifically known is that MCTD is a rare autoimmune disease that presents itself in men and women in their thirties and forties, that women are more susceptible to the disease than men, and that there is a genetic component.

Respondent produced no epidemiological evidence. Petitioner produced epidemiological studies and the testimony of Dr. Lamm, a well-qualified epidemiologist, who testified that none of the epidemiology studies to date had revealed any causal relationship between women who had breast prostheses (of all kinds by all manufacturers) and MCTD.[3]

At the conclusion of the liability phase of the case, petitioner moved for a directed verdict, which was denied. The jury returned its special and general verdicts finding petitioner liable for respondent's personal injuries. ER 283. Thereafter, the jury returned special verdicts awarding respondent total compensatory damages of $840,000. ER 299. The court then gave the jury instructions on punitive damages set forth in full in the margin.[4]

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[3] Dr. Lamm testified that, based on the number of women in the country who had such prostheses, epidemiologists would have expected at least 100 cases of MCTD to be reported in implant recipients if a causal connection existed, but, as of 1991, there was not even one such case reported in the United States.

[4] "You must now determine whether you should award punitive damages against defendant Dow Corning Corporation, for the sake of example and by way of punishment. Whether punitive damages should be imposed, and if so, the amount thereof, is left to your sound discretion, exercised without passion or prejudice.

The jury returned its verdict awarding $6,500,000 in punitive damages. ER 299. Judgment was entered in accordance with the verdicts on January 9, 1992. ER 309, App. 40. (Appendix C).

Petitioner moved for judgment notwithstanding the verdicts and, alternatively, for a new trial, on grounds that included the following: (1) The testimony of respondent's expert causation witnesses was insufficient to support the verdicts because none of their opinions was based on scientifically acceptable methodology, none of their methods was accepted by a relevant scientific community, and none was scientifically reliable. (2) The jury's awards of compensatory damages for medical expenses, loss of income, and pain and suffering were not sustained by the evidence because those awards included compensation for injuries and losses that were not causally related to her MCTD, the basis of her personal injury claim, and, in any event, were foreclosed by limitations. (3) The punitive damage award was excessive and bore no reasonable relationship to compensable damages. The

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"If you determine that punitive damages should be assessed against the defendant, in arriving at the amount of such an award, you must consider: (1) The reprehensibility of the conduct of the defendant. (2) The amount of punitive damages which will have a deterrent effect on the defendant in the light of defendant's financial condition. (3) That the punitive damages must bear a reasonable relation to the injury, harm, or damage actually suffered by the plaintiff." ER 302. The instruction was taken verbatim from the *California Approved Jury Instructions*: Civil No. 14.72.2 (rev. ed. 1989).

Immediately after giving that instruction, the district court told the jury: "The parties have stipulated that the net worth of defendant Dow Corning Corporation is $948,500,000." ER 302.

district court denied the motions on May 8, 1992. App. 32. (Appendix B).

Appeal. The case was briefed and argued after this Court had granted *certiorari* in *Daubert*, but before that opinion had come down. Petitioner argued, *inter alia*, that the district court prejudicially erred dènying summary judgment and in admitting over objection the testimony of respondent's expert causation witnesses because their testimony did not meet the criteria for admissibility under the *Frye* test, which was then the law of the Ninth Circuit, or the scientific reliability standards that had been accepted in the Second and Third Circuits.[5]

Petitioner attacked the jury's award of compensatory damages because the amounts vastly exceeded any damage that she could have suffered from such claims, if any, that were not barred by California limitation's law and because those damages were not proved to be causally related to her MCTD. It challenged the punitive damage award because it was grossly excessive, bore no understandable relationship to compensatory damages that could have been properly awarded, and the standards and procedure used to guide the jury's discretion in awarding punitive damages did not meet the constitutional minima required by *Pacific Mut. Life Ins. Co. v.*

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[5] After citing the relevant authorities from the Ninth and other circuits, petitioner urged reversal because respondent's testimony on the issue of causation "was not based on accepted scientific standards and was not reliable and because [respondent] could not meet her burden of proving that the prostheses caused the diseases and disorders of which she complained." Appellant's Opening Brief at 49.

Haslip, 499 U.S. 1, 113 L. Ed. 2d 1, 22, 111 S. Ct. 1032 (1991).[6] Appellant's Opening Brief at 57.

The case was orally argued on June 18, 1993. After the case was submitted, this Court decided *Daubert*, and the parties filed supplemental briefs discussing the impact of *Daubert* on the pending appeal. Petitioner's supplemental brief pointed out that the district court had declined to conduct the preliminary assessment of scientific reliability required by *Daubert*, and the testimony of respondent's expert witnesses did not meet the reliability criteria therein described. The panel issued its opinion on August 26, 1994.

Petitioner timely filed its petition for rehearing and suggestion for *en banc* consideration. The petition called the court's attention to the irreconcilability of the panel's holding and quoted *Daubert's* requirement that a Rule 104(a) preliminary assessment of scientific reliability was required:

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the

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[6] Petitioner also brought to the court's attention the pendency of two cases in which hearings had been granted by the California Supreme Court challenging, on due process grounds, California's procedures and standards for awarding punitive damages by juries. The petitions were later dismissed without explanation.

> reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. 509 U.S. at ___, 125 L. Ed. 2d at 482, 113 S. Ct. at ___.[7]

Petitioner also quoted from the panel's opinion:

> "[Petitioner] asserts that the district court erred in not holding a formal hearing. We disagree. The district court is not required to hold a Rule 104(a) hearing, but rather must merely make a determination as to the proposed expert's qualifications." 33 F.3d at 1124.

The petition also pointed out that the opinion relied on procedures and on factual assumptions that were

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[7] Footnote 11 omitted. Footnote 10 to the quoted passage states, in pertinent part:

> Rule 104(a) provides:
>
> "Preliminary questions concerning the qualification of a person to be a witness . . . or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. . . . " See *Bourjaily v. United States*, 483 U.S. 171, 175-76, 99 F.2d 144, 107 S. Ct. 2775 (1987). These matters should be established by a preponderance of proof.

Bourjaily concerned the admissibility of hearsay statements by an alleged co-conspirator implicating the defendant in a drug sale. The court explained that before the evidence could be admitted over objection, the court must previously "have found it more likely than not that the technical issues and policy concerns addressed by the Federal Rules of Evidence have been afforded due consideration." 483 U.S. at 175, 97 L. Ed. 2d at 152, 107 S. Ct. at 2778.

unsupported by the record in affirming the punitive damage award.[8]

The petition for rehearing was denied on October 11, 1994. App. 42. (Appendix D).

REASONS FOR GRANTING THE WRIT

A. The National Importance of the Admissibility of Proffered Expert Scientific Testimony

Hundreds of products liability cases are currently pending in federal courts in which the key liability issue is whether a prescription medical device or drug is causally related to plaintiff's diseases or illnesses, and, in each of them, the crucial liability question is the admissibility of expert scientific testimony on causation. The judgment in the district court in this case triggered the explosion of breast implant litigation. Before then, only a handful of

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[8] In affirming punitive damages, the petition explained that the opinion stated a number of assumed facts that were supported only by the arguments of respondent's counsel. After stating that petitioner's prostheses had been implanted in thousands of women, the opinion states: "Each of these women was at risk of encountering the same fate from which Hopkins suffered"; and "the evidence that [petitioner] gained financially from its conduct, may properly be considered in imposing an award of punitive damages." 33 F.3d at 1127. There was no evidence that any women, let alone thousands, were at risk of MCTD who had been implanted with petitioner's prostheses. The record contradicts the statement that petitioner gained financially; the evidence was that petitioner lost money on its sales of mammary prostheses.

breast implant cases had been filed against any manufacturer of such products anywhere in the country. Thereafter, state and federal courts have been inundated with cases, including class actions, against all manufacturers of mammary prostheses in which plaintiffs claim that whatever injury, disease or illness from which they suffer is causally related to their implants.

Mass product liability litigation, whether involving prescription drugs and medical devices or non-prescription products, share common characteristics and follow a well-documented pattern.[9] The genesis of such litigation

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[9] Numerous scholarly articles have discussed the features of the mass tort litigation phenomenon. Well-known examples of the products involved in the phenomenon include Bendectin, the Dalkon Shield, DES, swine flu vaccine, Agent Orange, and asbestos. The forces that have converged to create the situation include the intensity of media coverage, the strong organization of the plaintiffs' product litigation bar, the legalization of lawyers soliciting clients in such cases through media advertising, and the lure of potential multimillion dollar punitive damage verdicts against target defendants who have or are believed to have deep pockets. A few examples of the relevant literature are: L. Brickman, "On the Relevance of the Admissibility of Scientific Evidence: Tort System Outcomes are Principally Determined by Lawyers' Rates of Return," 15 *Cardozo L. Rev.* 1755 (1994); J.B. Weinstein, "Ethical Dilemmas in Mass Tort Litigation," 88 *Nw. U.L. Rev.* 469, 480 (1994) ("[t]he speed with which the number of breast implant cases exploded on the scene is attributable in part to a well-organized plaintiffs' bar, which now has the capital, organizational skills, and advertising techniques to seek clientele"); P. Huber, "Safety and the Second Best: The Hazards of Public Risk Management in the Courts," 85 *Colum. L. Rev.* 277 (1985); S. Sugarman, "Doing Away with Tort Law," 73 *Calif. L. Rev.* 555 (1985); J. Sanders, "The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts," 43 *Hastings L.J.* 301 (1992).

is usually one case in which a plaintiff has won a jury verdict that included large punitive damages against the manufacturer of a product and in which the case has received extensive media coverage. Breast implant litigation has followed the same pattern; it strikingly resembles the history of the bendectin litigation, the prescription product involved in *Daubert*.[10]

In all of these cases there is always a temporal connection between the claimed injury, disease or illness and the use of or exposure to the product. The key liability question is whether the product caused the plaintiff's condition, proof of which requires expert scientific testimony on that ultimate fact. The admissibility of proffered expert testimony is thus crucial to the outcome of the case.[11]

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[10] The Bendectin litigation began with a 1977 Florida lawsuit in which a mother claimed that her taking prescribed Bendectin during her pregnancy caused birth defects in her infant. *Mekdeci v. Merrill National Lab.*, 711 F.2d 1510 (11th Cir. 1983). *Mekdeci* received substantial media attention, and shortly thereafter, hundreds of lawsuits were filed in state and federal courts by women whose infants had birth defects. The same phenomenon occurred in breast implant litigation, except that media attention has been far more extensive and prolonged.

[11] The importance of the proper interpretation and application of *Daubert*, of course, is not limited to product liability litigation. The same issue arises in every case, civil or criminal, in which expert scientific or quasi-scientific testimony will be relied upon to prove an essential fact. *See, e.g. United States v. Rincon*, 984 F.2d 1003 (9th Cir.), *vacated and remanded for further consideration in the light of Daubert*, ___ U.S. ___, 126 L. Ed. 2d 12, 114 S. Ct. 41 (1993); *United States v. Rincon*, 11 F.3d 922 (9th Cir. 1993) (second opinion after remand.)

Even before *Daubert*, it should have been clear that trial judges have the duty to make a preliminary assessment of the admissibility of proffered expert testimony. Some trial judges, uncomfortable in the realm of scientific technique and methodology, have failed to perform that duty even though the same judges routinely perform their gatekeeping duty in deciding admissibility questions that are as hard.[12] The *Daubert* Court recognized that reality in observing: "We are confident that federal judges possess the capacity to undertake this review." 509 U.S. at ___, 125 L. Ed. at 482, 113 S. Ct. at ___. Whatever doubts individual judges may from time-to-time have entertained about their capacity to undertake a preliminary assessment of the scientific reliability of expert testimony, they are better situated to make that determination than jurors because jurors, unlike federal judges, are not empowered to appoint their own experts.

The briefs of the parties and the cascade of *amicus curiae* briefs filed in *Daubert* leave no doubt about the depths of concern expressed by litigants, scientists, and interested members of the general public that district judges must meticulously perform their gatekeeping role to prevent "junk science" from being introduced into evidence.

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[12] For example, trial judges regularly rule on the admissibility of hearsay even though the application of the hearsay rule and its exceptions is often difficult. The concerns about the admissibility of hearsay testimony are similar to the concerns expressed in *Daubert* about the admissibility of proffered scientific expert testimony: Is the testimony reliable? Does its probative value outweigh its prejudicial effect?

Strong considerations of public policy dictate that the preliminary assessment be made before trial, especially in cases, like this one, that have the potential for generating mass product liability litigation, the costs of which are astronomical.[13] If a plaintiff is not able to carry her burden of proof on the causation issue before trial, the action should end in the district court, thereby permitting the admissibility question to be reviewed on appeal by the fastest available means at the least cost to the litigants and to the judiciary.

B. The National Importance of the Standards of Judicial Review of Punitive Damages in Diversity Cases

This Court has repeatedly recognized the constitutional dimensions of the raging debates over unconstrained jury discretion in awarding punitive damages. The problem was succinctly posed in *Honda Motor Co.,*

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[13] The overburden on judicial systems from mass product liability actions can scarcely be overestimated. The General Accounting Office published a study for the decade 1976-1986 that toxic litigation (Bendectin, Dalkon Shield, and asbestos) accounted for over 60 percent of the total growth in filings during that decade, and those estimates did not include the broader range of products with the same characteristics. *GAO Briefing Report to the Chairman, Subcommittee on Commerce, Consumer Protection and Competitiveness, Committee on Energy and Commerce, House of Representatives: Products Liability Extent of "Litigation Explosion" in Federal Courts Questioned,* 2-3, 20-28 (1988). *See, e.g., In Re Joint E.&S. Dist. Asbestos Litig.,* 129 B.R. 710, 953 (E&S. D.N.Y. 1991), *vacated on other grounds,* 982 F.2d 721 (2d Cir. 1992) (excluding legal fees, asbestos litigation cost between 13 and 16 billion dollars).

Ltd. v. Oberg, ___ U.S. ___, 129 L. Ed. 2d 336, 114 S. Ct. 2331 [62 U.S.L.W. 4627] (1994):

> Punitive damages pose an acute danger of arbitrary deprivation of property. Jury instructions typically leave the jury with wide discretion in choosing amounts, and the presentation of evidence of a defendant's net worth creates the potential that juries will use their verdicts to express biases against big businesses, particularly those without strong local presences. ___ U.S. at ___, 129 L. Ed. 2d at 349, 114 S. Ct. ___, 62 U.S.L.W. at 4631.

This case exactly fits that description. Petitioner is a big corporation with no significant presence in California. Juries in California are given great discretion in imposing punitive damages. Unlike Alabama and Oregon, California law provides no post-trial constraints on such awards. Because this is a diversity case, judicial review of a punitive damage award is controlled by federal, not state law. Under *Browning-Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257, 106 L. Ed. 2d 219, 109 S. Ct. 2909 (1989), a federal court reviewing a punitive damage award in a diversity case must follow Rule 59 of the Federal Rules of Civil Procedure.[14] The Ninth Circuit applied neither the law of California nor Rule 59. Instead, it applied the post-trial constraints adopted by the State of Alabama that do not exist either in California law or federal procedural

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[14] Rule 59 provides, in pertinent part: "(a) A new trial may be granted to all or any of the parties and on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States. . . . "

rules. The court could not avoid the due process issue by amending California law and federal procedure rules.

Thus, this case presents the question: What standards of review are required to satisfy procedural due process when a jury award of punitive damages in a diversity case is attacked on due process grounds?[15]

C. The Ninth Circuit's Interpretation of *Daubert* Conflicts with the Opinions of Other Circuits

The Ninth Circuit specifically held that the only assessment that the district court was required to make before admitting the testimony of respondent's expert witnesses was the witnesses' qualification to testify and that no Rule 104(a) hearing is required. The panel undertook no review of the evidence presented by respondent to controvert petitioner's summary judgment motion challenging the sufficiency of her causation evidence to raise a triable issue of fact. If it had compared respondent's deposition testimony on causation with the requirements of *Daubert*, it should have been evident that her causation evidence was insufficient to permit her to go to trial. Without any comparison of the testimony that respondent's experts actually gave at pretrial and trial, the court summarily held that the respondent's witnesses

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[15] The Court noted the importance of that question in the context of its own review of state court judgments in *Honda Motor Co.*: "This case does not pose the more difficult question of what standard of review is constitutionally required." ___ U.S. at ___ n.10, 129 L. Ed. 2d at 350 n.10, 114 S. Ct. at ___, 62 U.S.L.W. at 4631.

were qualified and that their testimony was based on scientifically valid methodology. 33 F.3d at 1125.[16]

The Fifth, Sixth, Seventh and Eighth Circuits have all upheld summary judgments when the plaintiff's expert scientific witnesses did not meet *Daubert's* criteria for admissibility. *E.g., Wheat v. Pfizer, Inc.*, 31 F.3d 340 (5th Cir. 1994) (manufacturers of two prescription drugs prevailed on summary judgment in a wrongful death diversity case in which plaintiff claimed that the decedent's hepatitis was caused by the drugs because the proffered testimony of plaintiff's expert witness was based only on the witness' hypothesis that had not been subjected to peer review or publication and was unsupported by accepted methodology); *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1070-71 (6th Cir. 1993) (summary judgment for defendant affirmed in a Bendectin case because plaintiff's affidavit in opposition to summary judgment failed to show that the expert causation testimony was sufficiently reliable to raise a triable issue of fact); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090 (7th Cir. 1994) (testimony of plaintiff's expert witness that his cataracts

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[16] The opinion relied on the arguments of counsel, not on the testimony in the record. It recites the supposed expertise of Dr. Lappé and states that Dr. Kossovsky testified that "[t]he methodology used by Hopkins' experts in reaching their conclusions dated back to 1976"; and it also said that Dr. Kossovsky's opinion was based on "his participation in the preliminary epidemiological study involving over 200 women, and that Dr. Vasey based his opinion on "preliminary results of an epidemiological study and medical literature." 33 F.3d at 9787. The record supports none of those statements, as petitioner pointed out in its petition for rehearing.

were caused by overexposure to radiation from defendant's nuclear power plant resting only on the expert's observation and opinion, but otherwise unsupported by any scientific methodology was inadmissible); *Sorensen v. Shaklee Corp.*, 31 F.3d 638 (8th Cir. 1944) (summary judgment for defendant affirmed in an action claiming that the mental retardation of infants was caused by parents' ingestion of a product containing a chemical residue that was teratogenic or mutagenic; although qualifications of plaintiffs' expert witnesses to testify were unchallenged, their testimony was not based on a tested methodology and did not meet *Daubert's* reliability criteria).[17] *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607 (7th Cir. 1993) (plaintiff claimed that his kidney failure was caused by defendant's prescribed drug; summary judgment for the pharmaceutical company was affirmed because the proposed expert testimony was not properly grounded on the scientific method).

The method that respondent's expert witnesses used in reaching their conclusions had never been tested by anyone or peer reviewed. The risks of error in their methodology were neither quantified nor quantifiable, and none had been accepted by any scientific community. Accordingly, petitioner's summary judgment motion should have been granted. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 91 L. Ed. 2d 265, ___, 100 S. Ct. 2548, 2553

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[17] The *Sorensen* court explained that the plaintiff's expert witnesses had turned scientific analysis on its head: "Instead of reasoning from known facts to reach a conclusion, the experts here reason from an end result in order to hypothesize what needed to be known but was not." 31 F.3d at 649.

(1986). Petitioner's trial objections to the admission of respondents' expert witnesses should have been sustained.

When expert scientific testimony has been admitted, over objection, at trial, other circuits have meticulously compared the testimony actually given with the reliability criteria of *Daubert* to determine whether the evidence was sufficiently reliable to go to the jury. The Ninth Circuit did not do so. *Contrast United States v. Bonds*, 12 F.3d 540 (6th Cir. 1993); *United States v. Martinez*, 3 F.3d 1191 (8th Cir. 1993).[18]

D. The Ninth Circuit Violated *Browning-Ferris* and Impaired Petitioner's Procedural Due Process Rights by Adding Standards to Constrain Discretion in Awarding Punitive Damages that do not Exist in California or Federal Law

Although the opinion stated the requirements of *Browning-Ferris* (the district court had to decide whether the jury's punitive damage verdict was within the confines set by California law, and judicial review of the award is controlled by Federal Rule of Civil Procedure 59), it thereafter violated the very principles recited. It

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[18] Even before *Daubert*, other courts examined expert scientific testimony in detail to decide whether it was sufficient to go to the jury. *E.g.*, *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ___, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 315 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046, 108 L. Ed. 2d 646, 110 S. Ct. 1511 (1990). *Turpin* and *Brock* were cited with approval in *Daubert*, 509 U.S. at ___, 125 L. Ed. 2d at 484-85.

did not examine either California law or federal law. Instead, it applied the post-trial judicial standards of review adopted by Alabama set forth in *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22, 113 L. Ed. 2d 1, 22, 111 S. Ct. 1032, 1054 (1991).

A California jury receives little more instruction than that described in *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350, 41 L. Ed. 2d 789, 94 S. Ct. 2997 (1974):

> In most jurisdictions jury discretion over the amounts awarded is limited only by the general rule that they not be excessive. Consequently, juries assess punitive damages in wholly unpredictable amounts bearing no necessary relation to the actual harm caused.

The sole guidance given a California jury invited to award punitive damages is contained in the jury instruction given in this case.[19] California has not adopted any of Alabama's post-trial standards of judicial review.[20]

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[19] The entire text of the instruction is quoted in n.4 at pp. 4-5, *supra*. In *Adams v. Murakami*, 54 Cal.3d 105, 112, 284 Cal.Rptr. 318 (1991), the court candidly described the breadth of the jury's discretion in determining the amount of punitive damages to award:

> The determination of whether an award is excessive is admittedly more art than science. "The channeling of just the correct quantum of bile to reach the correct level of punitive damages is, to put it mildly, an unscientific process complicated by personality differences." [Citation omitted.]

[20] The *Adams* court recognized that California's post-trial review may not meet *Haslip*'s constitutional minima, but it postponed that decision because it had reversed on other grounds. 54 Cal.3d at 118-19 n.9.

Post-trial scrutiny is limited to examining the amount of the award to ascertain whether it appears to be excessive as a matter of law or whether it is so grossly disproportionate to compensatory damages and to the particular conduct charged as to raise a presumption that it is the result of passion or prejudice. *Neal v. Farmers Ins. Exchange*, 21 Cal.3d 910, 928, 148 Cal.Rptr. 389 (1978). *Neal* was reaffirmed in *Adams*.

Rule 59 does not provide any meaningful judicial scrutiny of punitive damage awards; the lack of such standards denied petitioner procedural due process of law.[21] Rule 59 provides no more post-trial scrutiny of punitive damage awards in diversity cases than did the procedures of Vermont and Mississippi about which the Justices expressed constitutional concern in *Browning-Ferris* and *Bankers Life & Casualty Co. v. Crenshaw*, 486 U.S. 71, 108 S. Ct. 1645, 100 L. Ed. 2d 62 (1988).

"The authority to grant a new trial . . . is confided almost entirely to the exercise of discretion on the part of the trial court." *Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36, 66 L. Ed. 2d 193, 197, 101 S. Ct. 188, ___ (1980). Appellate review does not constrain the district court's discretion or the jury's discretion with respect to punitive damage awards because appellate review is limited to an abuse of the district court's discretion. *Fairmount Glass*

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[21] In pertinent part, Rule 59 provides: "(a) *Grounds*. A new trial may be granted to all or any of the parties and on all or part of the issue (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States."

Works v. Cub Fork Coal Co., 287 U.S. 474, 77 L. Ed. 439, 53 S. Ct. 252 (1933). A district court does not abuse its discretion in upholding a punitive damage award unless the appellate court decides that the verdict was the result of passion, bias, or prejudice, or other improper motive or was so excessive as to shock the appellate judicial conscience. *E.g., Superbird Farms, Inc. v. Perdue Farms, Inc.*, 970 F.2d 238 (7th Cir. 1992); *Auster Oil & Gas, Inc. v. Stream*, 835 F.2d 597 (5th Cir. 1988); *Nairn v. National R.R. Passenger Corp.*, 837 F.2d 565 (2d Cir. 1988); *Whitely v. OKC Corp.*, 719 F.2d 1051 (10th Cir. 1983); *Community Television Services, Inc. v. Dresser Industries, Inc.*, 435 F. Supp. 214 (D.S.D. 1977), *aff'd*, 586 F.2d 637 (8th Cir. 1978); *Bonn v. Puerto Rico Int'l Airlines, Inc.*, 518 F.2d 89 (1st Cir. 1975).

This Court has relied heavily on the lengthy history of the common law relating to punitive damage awards in deciding whether punitive damage standards applied in state courts comply with due process. Common law is irrelevant in determining whether federal procedural law provides for meaningful judicial scrutiny of punitive damage awards in diversity cases for the obvious reason that the common law has nothing to say about federal procedural rules.

The plain truth is that federal judicial review of punitive damages in diversity cases provides no "definite and meaningful constraint on the discretion of [California] factfinders in awarding punitive damages." *Haslip*, 499 U.S. at 22, 113 L. Ed. 2d at 22, 111 S. Ct. at 1054. Unlike Alabama plaintiffs, California plaintiffs do "enjoy a windfall because they have the good fortune to have a defendant with a deep pocket." *Ibid.* Respondent and her lawyers have enjoyed just such a windfall.

With exceptions not here pertinent, a district court cannot overturn a jury's discretion in awarding punitive damages in diversity cases, and appellate courts must defer to the district court's discretion without exercising discretion of their own. Three levels of standardless discretion have brought to fruition the danger of which this Court warned in *Honda Motor Co.*.

E. The Circuits are in Conflict on the Application of *Haslip* to Punitive Damage Awards in Diversity Cases

No less process is due under the Fifth Amendment than under the Fourteenth Amendment. Yet, federal appellate courts have been unable to agree on the correct application of *Haslip* in diversity cases. The Fourth Circuit is in conflict with the Ninth, and the Eighth Circuit is on a different tack from either one.

In *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95 (4th Cir. 1991), the issue arose in a diversity action for personal injuries suffered in an automobile collision in South Carolina. The jury awarded the plaintiffs compensatory damages of $75,000 and punitive damages of $100,000. The district court denied post-trial motions for judgment NOV, a new trial, and a remittitur. On appeal, the defendant challenged the punitive damages award on due process grounds. Unlike Alabama, South Carolina had no post-verdict standards of review. Relying on *Haslip*, the court held that the lack of standards constraining discretion deprived defendant of due process. Contrary to the Ninth Circuit, the Fourth Circuit followed *Browning-Ferris*:

> The legitimizing constraints provided by the quasi *de novo* review process practiced under Alabama state law cannot be applied by a federal district court. While a district court must apply the substantive law of the state when instructing the jury on punitive damages, *see Erie R.R. Co. v. Tompkins*. 304 U.S. 64, 58 S. Ct. 817, 82 L. Ed. 1188 (1938), it must also apply the Federal Rules of Civil Procedure and, therefore, must review the jury verdict under standards established by Rules 50(b) (directed verdict and j.n.o.v.) and 59 (new trial). Moreover, the review by a federal district court of a jury verdict is always subject to the Seventh Amendment constraints guarantying the right to a jury trial which are not imposed on any state-prescribed post-trial review. This division in the application of substantive state law and federal procedural law is specifically confirmed in *Browning-Ferris*. . . . 947 F.2d at 99.

The South Carolina law relating to punitive damage awards closely resembles that of California. The only constraint on the award by the jury is provided by the discretion given to the district court to review the award for excessiveness.

After the case had been orally argued, but before its opinion came down, the Supreme Court of South Carolina adopted post-trial review standards similar to those in Alabama. The Fourth Circuit explained that the district court could not itself apply those standards on retrial because it had to apply Rules 50(b) and 59 of the Federal Rules of Civil Procedure. To resolve the dilemma posed by the Seventh Amendment, the Court remanded the case

to the district court with directions to instruct the jury in accordance with South Carolina's post-trial standards.

The Eighth Circuit took a different view from the Fourth in *Latham Seed Co. v. Nickerson American Plant Breeders, Inc.*, 978 F.2d 1493 (8th Cir. 1992), a diversity case, in which the plaintiff claimed damages for breach of an oral contract and for fraud invoking state law. The Eighth Circuit had earlier remanded the same case to the district court after *Haslip*; on remand, the district court reviewed the punitive damage awards by applying the post-review standards of Alabama. The district court thereafter held that the damage awards were proper, and this appeal followed.

Without addressing the question whether the district court could apply standards that had never been adopted by the state, the law of which was controlling, and without considering Rule 59, the court upheld the district court on the theory that "the district court's additional scrutiny of the award under the seven *Haslip* factors helps to ensure that the jury's verdict satisfied due process requirements." 978 F.2d at 1501.

CONCLUSION

The questions herein presented are ripe for this Court's determination. Petitioner prays that this Court will grant *certiorari* in this case.

Dated: November 10, 1994

Respectfully submitted,

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Admitted to the Bar
of the Supreme Court
on January 8, 1962

No. 94-___

In The

Supreme Court of the United States

October Term, 1994

MARIANN HOPKINS,

Plaintiff-Appellee-Respondent,

v.

DOW CORNING CORPORATION,

Defendant-Appellant-Petitioner.

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MARIANN HOPKINS, Plaintiff-Appellee v. DOW CORNING CORPORATION, Defendant-Appellant	NO. 92-16132 D.C. No. CV-88-04703-TEH OPINION

Appeal from the United States District Court
for the Northern District of California
Thelton E. Henderson, Chief District Judge, Presiding

Argued and Submitted
June 18, 1993 – San Francisco, California

Filed August 26, 1994

Before: Donald P. Lay,* Procter Hug, Jr., and
Mary M. Schroeder, Circuit Judges.

Opinion by Judge Hug

SUMMARY

* Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

**Civil Litigation and Procedure/
Statutes of Limitation/ Torts**

The court of appeals affirmed a district court judgment. The court held that the district court correctly found that, under California's delayed discovery rule, a plaintiff's action for injuries suffered as a result of silicone breast implants was not barred by the applicable statute of limitations.

In 1976, appellee Mariann Hopkins had reconstructive surgery on her breasts. Silicone gel implants manufactured by appellant Dow Corning Corporation were utilized. Due to complications, the left implant was removed in 1976. In 1977, replacement implants, also manufactured by Dow, were inserted.

In 1979, Hopkins was diagnosed with mixed connective tissue disease (MCTD). In 1986, due to further complications from her breast implants, Hopkins underwent surgery. At that time, Hopkins' doctor discovered the implants had ruptured, and he proceeded to remove silicone gel that had escaped.

The ruptured implants were sent to Dow for analysis. In a report, Dow responded that it found no evidence to indicate that any of the damage was related to manufacture. None of Hopkins' physicians informed her that the ruptured implant could be responsible for her connective tissue disease.

In December, 1987, Hopkins learned from her mother that a possible connection between the ruptured implants and the immune disorder might exist. Hopkins' physician, however, informed her that he had never heard of such a connection. In 1988, another doctor was also

unable to provide information regarding a possible causal connection.

On December 1, 1988, Hopkins filed a diversity action against Dow, alleging fraud, strict products liability, and breach of express and implied warranties. On cross motions for summary judgment, the district court ruled that Hopkins' suit was timely filed.

Evidence presented during the liability phase of the trial indicated that Dow rushed development of the implants, failed to adequately test them, and ignored knowledge of adverse health consequences associated with them. Evidence further indicated that in addition to evidence of silicon leakage, Dow implants experienced a high rate of rupture. There was also evidence that no research concerning long-term health effects had been conducted. Other evidence indicated that Dow had knowledge of harmful effects of silicone on the human body. The district court denied Dow's motion in limine attacking the admissibility of the testimony of Hopkins' expert witnesses.

A jury returned a special verdict finding Dow liable on all of Hopkins' theories. After a second trial pertaining to damages, the jury awarded Hopkins $840,000 in compensatory damages and $6.5 million in punitive damages.

Dow appealed, contending that Hopkins' strict liability and breach of warranty claims were barred by California's one-year statute of limitations for personal injury claims. Dow also contended that the district court erred in denying its motion attacking the admissibility of Hopkins' experts' testimony. Dow further contended that an exception from strict liability for manufacturers of

prescription drugs applied. Finally, Dow also challenged the size of the damage awards.

[1] Under California's discovery rule, the accrual date of a cause of action is delayed until the plaintiff is aware of her injury and its negligent cause. [2] Hopkins pled the facts necessary to invoke the discovery rule; she alleged that prior to December 1, 1987 she never had any reason to suspect that her silicone breast implants were the wrongful cause of her MCTD; [3] in addition, deposition testimony of doctors showed that they did not inform her of the link between the implants and her disease; [4] moreover, Hopkins testified that her review of Dow's report convinced her that the implants were not defective. Facts, therefore, demonstrated Hopkins' time of discovery and further demonstrated circumstances excusing her delayed discovery.

[5] Dow failed to set forth specific facts indicating that when Hopkins first learned that the implants had ruptured in 1986, Hopkins actually suspected that she had been injured and that her injury was caused by wrongdoing. [6] In the absence of specific factual evidence, there could be no triable issue of fact as to whether Hopkins actually knew that she had been injured and that her injury was caused by wrongdoing. [7] Furthermore, Dow failed to present specific facts to create a genuine issue of material fact as to whether Hopkins should have suspected that she had been injured and that her injury was caused by wrongdoing in 1986.

[8] The uncontradicted facts demonstrated that prior to December 1987, Hopkins neither suspected nor should have suspected that she had been injured or that

any injury was caused by wrongdoing. Accordingly, the applicable statute of limitations was tolled until Hopkins' discovery in December 1987. The district court's order granting summary judgment in favor of Hopkins on this question was therefore proper.

[9] The knowledge, skill, and experience of Hopkins' experts was sufficient to qualify them as experts. [10] In addition, the "reasoning or methodology" underlying their testimony was "scientifically valid." [11] Accordingly, the district court's decision to admit the expert testimony was not an abuse of discretion.

[12] The strict liability exception for prescription drugs was inapplicable in this case. [13] The requirements for the exemption were not met; there was a failure to establish that the product was properly prepared or that the appropriate warnings were given. Thus, even if the prescription drug exemption were extended to implanted medical devices, the exemption would be inapplicable because the essential conditions of the special exemption were not met.

[14] Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award. Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, could properly be considered in imposing an award of punitive damages.

COUNSEL

Shirley M. Hufstedler, Hufstedler, Kaus & Ettinger, Los Angeles, California, for the defendant-appellant.

Laurence H. Tribe, Law Professor, Cambridge, Massachusetts, for the plaintiff-appellee.

OPINION

HUG, Circuit Judge:

In this diversity action, Mariann Hopkins sued Dow Corning Corporation to recover for injuries suffered as a result of two sets of breast implants manufactured by Dow, which she received in breast reconstruction surgeries in 1977 and 1986. The jury found Dow liable for Hopkins' injuries and awarded Hopkins $840,000 in compensatory damages and $6.5 million in punitive damages. Dow appeals.

Dow contends that the district court erred in determining that Hopkins' claims were not barred by the applicable statute of limitations. Dow challenges the district court's determination that the evidence presented at trial was sufficient to support a finding of fraud and further challenges the court's decision to admit the plaintiff's expert testimony on the issue of causation. Finally, Dow challenges the amount of both the compensatory and the punitive damages awards.

The district court's jurisdiction was based upon 28 U.S.C. § 1332(a)(1). We exercise jurisdiction over this timely appeal pursuant to 28 U.S.C. § 1291. We affirm.

I. FACTS

On October 4, 1976, plaintiff Mariann Hopkins underwent a bilateral subcutaneous mastectomy for severe fibrocystic disease at St. Mary's Hospital in San Francisco, California. Dr. Karl Bollinger performed the surgery. During the operation, Dr. Bollinger performed reconstructive surgery on plaintiff's breasts utilizing silicone gel implants manufactured by defendant Dow Corning.

Due to subsequent complications, Dr. Bollinger removed the left implant in November, 1976. In June, 1977, Dr. Bollinger inserted a replacement implant in the left breast and replaced the right breast implant in order to achieve symmetry. These implants were also manufactured by the defendant.

In March, 1979, Dr. Stephen Gospe diagnosed plaintiff with mixed connective tissue disease ("MCTD"). MCTD is a rheumatological disorder which includes symptoms such as extreme fatigue, weakness, muscle aches and pains, arthralgia, myalgia and arthritis. There is no known cure for this disease.

In January, 1986, plaintiff contacted Dr. Bollinger about further complications from her breast implants. Plaintiff underwent surgery in February to correct the problem. At that time, Dr. Bollinger discovered the implants had ruptured; during the four-hour operation, he proceeded to remove silicone gel that had escaped from the implant. The ruptured implants were sent to Dow for analysis. Several months later, Dow responded to Dr. Bollinger that "examination and testing of both

envelopes found no evidence to indicate that any of the damage was manufacture related." Dr. Bollinger informed plaintiff of these results.

None of plaintiff's physicians informed her that the ruptured implant could be responsible for the connective tissue disease from which she suffered. In December, 1987, plaintiff learned from her mother that a possible connection between the ruptured implants and the immune disorder might exist. Shortly thereafter, plaintiff inquired of her physician, Dr. Pelfini, if a possible causal link existed. Dr. Pelfini informed plaintiff that he had never heard of such a connection. In January, 1988, plaintiff visited another of her treating physicians, Dr. Gospe, and inquired the same of him. Dr. Gospe was also unable to provide information regarding a possible causal connection. Plaintiff filed her complaint on December 1, 1988, alleging fraud, strict products liability and breach of express and implied warranties, and requesting compensatory and punitive damages.

The case was bifurcated so that issues regarding liability would be determined first, and if needed, a second trial on damages would be held. The liability phase of the trial began on October 29, 1991. The evidence presented at trial indicated that Dow rushed development of the silicone gel implants, failed to adequately test the implants, and ignored knowledge of adverse health consequences associated with the implants. Plaintiff presented evidence that Dow created a Mammary Task Force charged with getting the new gel implant to market in less than five months. Even after a task force member presented his concerns about "a possible gel bleed situation" Dow ignored proposed design modifications that

would reduce the likelihood of leakage. The record indicates that Dow instructed salesmen to wash the implants with "soap and water" in the nearest rest room, and to "dry with hand towels as the implants become oily after being handled and [bleed] on the velvet in the showcase."

The evidence further indicated that in addition to the evidence of silicone leakage, Dow implants experienced a high rate of rupture. Despite proposals by one task force member to implement a "multiple dip" method as a means of ensuring greater uniformity in the envelope, and thereby less likelihood of rupture, Dow adopted the single dip method because it was "easier" and "cheaper." After an incident in which two of the new gel implants "broke during augmentation surgery for the TV taped demonstrations," Thomas Talcott, a Dow engineer, inquired of key Dow employees, "When will we learn at Dow Corning that making a product 'just good enough' almost always leads to products that are 'not quite good enough?' "

There was also evidence that no research concerning the long-term health effects had been conducted. The longest study to address possible adverse health effects of the implants took place over only 80 days and revealed evidence of inflammatory immune response caused by the gel. Dow continued to market these implants until 1987, without the benefit of a lifetime study to demonstrate the safety of its product.

Other evidence at trial indicated that Dow had knowledge of the harmful effects of silicone on the human body. Dow obtained results of a study in which four dogs received silicone gel implants that resembled

the implants that Dow was then marketing. The results demonstrated that after six months, the implants appeared to be functioning properly, but that after two years, inflammation surrounding the implants demonstrated the existence of an immune reaction. Dow did not publicly release the results of this research for several years, and when it did ultimately release the results, Dow omitted the negative findings and implied that the implants were safe.

Based on these facts, the jury returned a special verdict finding the defendant liable on all plaintiff's theories, including strict liability, breach of warranty, and fraud. The second trial, pertaining to the amount of damages, began on December 11, 1991. The jury awarded plaintiff $840,000 in compensatory damages and $6.5 million in punitive damages. The district court denied Dow's motion for a directed verdict. The district court also denied Dow's motions for judgment notwithstanding the verdicts and, alternatively, a new trial. Dow appealed.

II. STATUTE OF LIMITATIONS

Dow contends that Hopkins' strict liability and breach of warranty claims are barred by California's one-year statute of limitations for personal injury claims. Hopkins asserts that her claims were timely because they were filed pursuant to the "delayed discovery" doctrine.

[1] Hopkins and Dow agree that California Code of Civil Procedure § 340(3), which sets forth a one-year statute of limitations period for "an action . . . for injury to . . . one caused by the wrongful act or neglect of another," applies to the products liability and breach of

warranty theories alleged in this case. The parties also agree that the common law rule, which provides that a cause of action accrues on the date of the injury, applies except as modified by the discovery rule. Under California's discovery rule, the accrual date of a cause of action is delayed until the plaintiff is aware of her injury and its negligent cause. *Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 926-27 (Cal. 1988); *Frederick v. Calbio Pharmaceuticals*, 152 Cal.Rptr. 292, 294 (Ct. App. 1979). The parties disagree as to when Hopkins became aware of her injury and its wrongful cause and, thus, whether Hopkins initiated this action in a timely manner.

On cross motions for summary judgment, the district court ruled that Hopkins' suit was timely filed.[1] We review *de novo* the district court's determinations on summary judgment. *Jones v. Union Pac. R.R. Co.*, 968 F.2d 937, 940 (9th Cir. 1992); *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 629 (9th Cir. 1987). We must determine whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law. *Federal Deposit Ins. Corp. v. O'Melveny & Myers*, 969 F.2d 744, 747 (9th Cir. 1992), *cert. granted*, 114 S. Ct. 543 (U.S. Nov. 29, 1993); *Tzung v. State Farm Fire and Casualty Co.*, 873 F.2d 1338, 1339-40 (9th Cir. 1989).

Under California's discovery rule, "the statute of limitations begins to run when the plaintiff suspects or

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[1] In its motion for summary judgment, Dow argued that all of Hopkins' claims, except those based upon fraud and negligent misrepresentation, were time-barred.

should suspect that her injury was caused by wrongdoing, that someone has done something wrong to her." *Jolly*, 751 P.2d at 927. Plaintiff need not know the specific facts necessary to establish her claim. *Id.* at 928. Once plaintiff has " 'notice or information of circumstances to put a reasonable person on inquiry, or has the opportunity to obtain knowledge from sources open to [her] investigation, . . . the statute commences to run' " *Braxton-Secret v. A.H. Robins Co.*, 769 F.2d 528, 530 (9th Cir. 1985) (citation omitted). To invoke the discovery rule, plaintiff must plead facts which show "(1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Saliter v. Pierce Bros. Mortuaries*, 146 Cal.Rptr. 271, 274 (Ct. App. 1978) (citing *G.D. Searle & Co. v. Superior Court*, 122 Cal.Rptr. 218, 220 (Ct. App. 1975)).

[2] Hopkins pled the facts necessary to invoke the discovery rule. With respect to the time and manner of her discovery that her injury may have been caused by wrongdoing, Hopkins alleged in her complaint that prior to December 1, 1987, plaintiff never had any reason to suspect that her silicone breast implants were the wrongful cause of her MCTD.

In ruling on the cross motions for summary judgment, the district court granted Hopkins' motion and denied Dow's. Dow appeals both orders. Obviously, if Hopkins' motion was properly granted, Dow's was properly denied. We therefore initially consider the order granting Hopkins' summary judgment.

A party seeking summary judgment bears the initial burden of informing the district court of the basis for its

motion, identifying those portions of its pleadings, depositions, answers to interrogatories, admissions on file or affidavits that demonstrate an absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A dispute as to a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Hopkins concedes that she would have the burden of proof at trial that her discovery of the wrongdoing was within one year from the time she filed her action. Thus, in order to prevail on the motion for summary judgment, she had to show that Dow failed to present evidence sufficient to create a genuine issue of fact as to whether the action was filed within one year of the discovery of the wrongdoing. *See Celotex*, 477 U.S. at 322. The standard for granting a summary judgment is equivalent to the standard for granting a judgment as a matter of law under Fed. R. Civ. P. 50. *Id.* at 323.

[3] In her deposition, Hopkins testified that she learned of the possible connection between breast implants and autoimmune disease from her mother in December, 1987.[2] Thereafter, Hopkins asked Drs. Pelfini and Gospe about the possible connection. Like Dr. Bollinger's deposition testimony, the deposition testimony of Drs. Pelfini and Gospe shows that neither was aware of

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[2] The record does not reflect the circumstances surrounding Hopkins' mother's knowledge of the possible connection between MCTD and the breast implants, nor does the record suggest that Hopkins' mother learned of the connection prior to December, 1987.

or informed her of the link between the implants and her disease. Hopkins also testified that she had never read any news report or other article in any newspaper or magazine about the possible link between breast implants and autoimmune disease. Hopkins filed her complaint on December 1, 1988, within one year of her alleged discovery in December, 1987.

[4] With respect to the circumstances excusing delayed discovery, Hopkins asserted that when she first learned that the implants had ruptured in February, 1986, she had no reason to suspect that the rupture had caused her injury or that any injury was the result of wrongdoing. Hopkins testified that her review of Dow's Complaint Analysis Report convinced her that the implants were "not defective in any way." The report made no mention of medical research indicating a link between silicone and MCTD. Moreover, the report stated, as to both implants, that (1) "[t]he envelope displayed no abnormality in the area of the rupture" and (2) "[t]he thickness [of the implant envelope] is within the product specification limits." The report concluded that "[e]xamination and testing of both envelopes found no evidence to indicate that any of the damage was manufacture related." In response to requested discovery, Dow admitted that the report "does not state that the implants were defective in design" and "does not state that breast implants may rupture without cause following implantation." We conclude that these facts demonstrate Hopkins' time of discovery, and further demonstrate circumstances excusing her delayed discovery.

We must next consider whether Dow set forth specific facts sufficient to demonstrate the existence of a genuine issue of material fact for trial regarding the discovery rule. In reviewing an order granting summary judgment, we are limited to the facts shown in the affidavits, depositions, interrogatories, admissions, uncontested pleadings, and other evidence available to the court at the time the motion was made. *Jewel Companies v. Pay Less Drug Stores Northwest*, 741 F.2d 1555, 1559 (9th Cir. 1984).[3]

Dow contends that the statute started running in 1986 when Dr. Bollinger discovered the ruptured implants during the February, 1986 surgery, and that Hopkins was responsible for investigating the possibility of wrongdoing at that time. The injury for which Hopkins seeks recovery is the MCTD, which she contends was caused by the defective implants. Dow maintains that Hopkins manifested suspicion of wrongdoing by asking for Dow's laboratory analysis of the returned implants and, therefore, that she was obligated to undertake an investigation into the possibility of wrongdoing. Dow submits that a simple investigation would have revealed

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[3] An order granting summary judgment governs the future course of the trial, with the parties having considered the issue to be settled. This is to be distinguished from an order denying summary judgment, where the parties anticipate the production of further evidence on the issue of fact and may respond at trial. In that circumstance, the adequacy of the evidence to justify a jury's consideration of the issue is properly considered in the context of a motion for a judgment as a matter of law under Fed. R. Civ. P. 50. *See Stuckey v. Northern Propane Gas Co.*, 874 F.2d 1563, 1567 (11th Cir. 1989).

to Hopkins the possible connection between the implants and MCTD.

[5] We conclude that Dow failed to set forth specific facts indicating that when Hopkins first learned that the implants had ruptured in February, 1986, Hopkins actually suspected that she had been injured and that her injury was caused by wrongdoing. Dow did not point to any medical or testimonial evidence demonstrating that Hopkins was actually suspicious. Unlike the plaintiff in *Jolly*, Hopkins never stated that "she was interested in 'obtaining more information' about [the implants] because she wanted to 'make a claim;' she felt that someone had done something wrong to her concerning [the implants], that [they were] defective [prostheses] and that she should be compensated." *Jolly*, 751, P.2d at 929. Hopkins' statements were simple inquiries and not reflective of any suspicion of wrongdoing by Dow.

[6] The statements Hopkins made are contrary to those made in *Jolly* and are readily distinguishable from those made by the plaintiffs in the cases on which Dow relies. *See Miller*, 2 Cal. Rptr. 2d at 803 (on summary judgment, plaintiff expressly agreed that it was undisputed that the letter, which her husband sent to defendant almost two years before she filed her complaint, stated that the flooding caused mold which caused her injuries); *Gutierrez v. Mofid*, 705 P.2d 886, 888-89 (Cal. 1985) (the evidence on summary judgment made clear, and plaintiff conceded for purposes of argument, that she both knew of her injury and suspected malpractice almost immediately after the operation – almost two years before she filed suit); *Snow v. A.H. Robins Co., Inc.*,

211 Cal.Rptr. 271, 275 (Ct. App. 1985) (plaintiff's deposition testimony demonstrated that eight years prior to filing her complaint, she viewed the Dalkon Shield as responsible for her ultimate injuries); *Sidney-Vinstein v. A.H. Robins Co.*, 697 F.2d 880, 884 (9th Cir. 1983) (plaintiff testified at her deposition that she understood immediately after the hysterectomy, more than six years before she filed suit, that the Dalkon Shield had not done what it was supposed to do and that it had caused the infection). There has been no evidence presented that Hopkins ever made statements of this nature. In the absence of specific factual evidence, there can be no triable issue of fact as to whether Hopkins actually knew that she had been injured and that her injury was caused by wrongdoing.

[7] Furthermore, we also conclude that Dow failed to present specific facts to create a genuine issue of material fact as to whether Hopkins should have suspected that she had been injured and that her injury was caused by wrongdoing in February, 1986. Unlike the Dalkon Shield cases cited by Dow, this is not a case in which the only reasonable conclusion that Hopkins could have drawn was that the failure of the medical device to serve its purpose was the possible cause of her injury. *See Braxton-Secret*, 769 F.2d at 531 ("When she discovered, after suffering a miscarriage, that she had been pregnant while the IUD was still in place, the only reasonable conclusion she could have drawn was that the IUD failed its contraceptive purpose" and caused her pregnancy and incomplete spontaneous abortion); *Snow*, 211 Cal.Rptr. at 276 ("An abortion is an event sufficient to alert a victim

of unwanted pregnancy while using an IUD 'to the necessity for investigation and pursuit of her remedies.' ") (citation omitted).

Hopkins' case is drastically different from the Dalkon Shield cases discussed above. It is widely known that an intra-uterine device, like any contraceptive, is designed to prevent pregnancy. Further, it is commonly understood that there is a direct connection between contraceptives and pregnancy. In contrast, the purpose of breast implants is not to prevent autoimmune disease, and it is not commonly understood that there is any connection, let alone a direct connection, between breast implants and MCTD. The Dalkon Shield cases are simply inapposite.

Dow contends that if Hopkins had undertaken a simple investigation, she would have discovered the possible link between breast implants and MCTD. We reject this contention. Hopkins' review of Dow's Complaint Analysis Report certainly did not reveal to her the possible connection; the report made no mention of medical research indicating a link between silicone and autoimmune diseases. Further, Hopkins, a lay person, was unlikely to discover the single article from a professional medical journal[4] and two cases like Hopkins' case against Dow, which Dow identified in its moving papers. Unlike *Jolly*, this is not a case in which "a timely investigation

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[4] Dow identified an article entitled, "Human Adjuvant Disease, Possible Autoimmune Disease After Silicone Implantation: A Review of the Literature." The article appeared in the July, 1986 edition of *Plastic and Reconstructive Surgery*, a periodical published by the American Society of Plastic and Reconstructive Surgeons.

would have disclosed numerous articles concerning [the possible link between breast implants and autoimmune disease] [in lay publications] and many [breast implants] suits filed throughout the country alleging wrongdoing." *Jolly*, 751 P.2d at 929. As the district court accurately observed, the article and lawsuits cited by Dow were neither numerous nor notorious enough to put Hopkins on notice about her injury.

Any information that a "simple investigation" arguably would have revealed to Hopkins should have come from Dow itself. In responses to requests for admissions, Dow stated that there were "reports in the published medical literature of suspected immunological sensitization or hyperimmune system response to silicone mammary implants" as of May, 1986. However, Dow neglected to mention this association in its Complaint Analysis Report so that Hopkins could take appropriate action. Instead, Dow elected to suppress this information. A simple investigation would not have revealed the existence of this information, and none of Hopkins' physicians answered her questions with any information suggesting that such a link existed. We agree with the district court that "the Complaint Analysis Report issued by Dow encouraged, if not created, plaintiff's belief that defendant's product was not defective and that she was not injured" such that "[r]uling in defendant's favor here would therefore unjustly reward defendant for misleading consumers such as Ms. Hopkins." We conclude that any effort by Hopkins to determine whether there was wrongdoing or whether there existed a possible link between breast implants and autoimmune disease were

hampered by Dow, and that Hopkins' eventual discovery was made in spite of Dow.

[8] The uncontradicted facts presented in support of the motions for summary judgment demonstrate that prior to December, 1987, Hopkins neither suspected nor should have suspected that she had been injured or that any injury was caused by wrongdoing. Accordingly, we conclude that the applicable statute of limitations was tolled until Hopkins' discovery in December, 1987, and the district court's order granting summary judgment in favor of Hopkins on this question was proper.

III. ADMISSIBILITY OF EXPERT WITNESS TESTIMONY

Dow argues that the district court erred in denying Dow's motion in limine attacking the admissibility of the testimony of Hopkins' three expert witnesses. Dow maintains that the testimony on the issue of causation should have been excluded because it was not based on scientifically accepted standards. Further, Dow asserts that without the expert testimony, Hopkins would have been unable to satisfy her burden of proving that the implants caused her injuries. We review a district court's evidentiary rulings for abuse of discretion. *Roberts v. College of the Desert*, 870 F.2d 1411, 1418 (9th Cir. 1988).

When confronted with an offer of expert testimony, the trial judge must first determine, pursuant to Rule 104(a) and Rule 702, whether the expert is proposing to testify to scientific knowledge that will assist the trier of

fact in resolving a fact in issue.[5] Dow asserts that the district court erred in not holding a formal hearing. We disagree. The district court is not required to hold a Rule 104(a) hearing, but rather must merely make a determination as to the proposed expert's qualifications.

[9] Dow objects to the admission of testimony from Hopkins' three expert witnesses: Drs. Lappe, Kossovsky and Vasey. Dow asserts that Dr. Lappe was not qualified to testify as an expert because he was not qualified to recount a causal connection between Hopkins' implants and the disease from which she suffered. Hopkins contends that although Lappe is not a medical doctor, he is a nationally-renowned toxicologist who has served federal and state agencies as well as private organizations in determining the safety of substances and materials for use by human beings. With respect to Drs. Kossovksy and Vasey, Dow asserts that although they were medical doctors qualified to diagnose the cause of illness, neither was

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[5] Federal Rule of Evidence 104(a) provides:

> (a) Preliminary Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination, it is not bound by the rules of evidence except those with respect to privileges.

Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

qualified to testify to Hopkins' condition because neither had examined her. We conclude that the knowledge, skill, and experience of Hopkins' three experts was sufficient to qualify them as experts within the meaning of Rule 104(a). The district court's decisions were proper.

Dow further challenges the admissibility of Hopkins' experts' testimony on the basis that the experts' methodology was not based on generally accepted scientific principles. The admission of such expert testimony is controlled by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2796 & n.11 (1993). In *Daubert*, the Supreme Court held that the *Frye* "general acceptance" test was superceded by the adoption of the Federal Rules of Evidence. 113 S. Ct. at 2793. Focusing on the history of Rule 702, the Court stated, "[t]he drafting history makes no mention of *Frye*, and a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony.' " *Id.* at 2794 (citing *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)). In formulating an approach to Rule 702, the Court noted that the trial judge must ensure that any scientific testimony or evidence ultimately admitted is "not only relevant, but reliable." *Id.* at 2795. The Court stated that the expert's testimony must be based on "scientific . . . knowledge," implying a "grounding in the methods and procedures of science" and must connote "more than subjective belief or unsupported speculation." *Id.* The inquiry is to be a flexible one, and "must be solely on principles and methodology, not on the conclusions that they generate." *Id.* at 2797.

Thus, according to *Daubert* and Rule 702, the testimony of these experts need not be based on "generally accepted" methodologies, but rather must be based on "scientific knowledge" that will "assist the trier of fact." *Id.* at 2794, 2795; Fed. R. Evid. 702. The record reflects that Hopkins' experts based their opinions on the types of scientific data and utilized the types of scientific techniques relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review. The record demonstrates that Dr. Lappe is a recognized expert on the immunological effects of silicone in the human body. Specifically, Dr. Lappe testified that his opinion was based on his experience as a toxicologist, his review of medical records and Dow studies, and his general scientific knowledge of silicone's ability to cause immune disorders as established by animal studies and biophysical data.

Another of Hopkins' experts, Dr. Kossovsky, testified that the methodology used by Hopkins' experts in reaching their conclusions dated back to 1976. Specifically, he testified that his opinion was based on scientific studies he authored, his participation in a preliminary epidemiological study involving over 200 women, and his examination of Hopkins during which he discovered evidence of silicone in her tissue and detected symptoms consistent with exposure to silicone. He also testified to the presence of corroborating evidence found in studies conducted on animals.

[10] Dr. Vasey, a rheumatologist, testified that his opinion was based on medical records, his clinical experience, preliminary results of an epidemiological study and

medical literature. Thus, we conclude the "reasoning or methodology underlying the testimony is scientifically valid. . . . " *Daubert*, 113 S. Ct. at 2796.

[11] We conclude that Hopkins' experts' opinions were based on scientific techniques that satisfied the requirements established in *Daubert*. Accordingly, the district court's decision to admit the expert testimony was not an abuse of discretion.

IV. STRICT LIABILITY

Dow asserts that the district court erred in denying its motion in limine regarding the exemption from strict liability on the basis of comment K of the Restatement of Torts and the line of California cases which have followed its reasoning. Hopkins maintains that the exemption from strict liability provided by comment K has no applicability to the facts of this case. We agree with Hopkins that the claimed exception for manufacturers of prescription drugs is unavailable to Dow.

Comment K provides as follows:

> k. *Unavoidably unsafe product.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to

> physicians or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability. . . .

In *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), the California Supreme Court adopted this approach in exempting the manufacturers of prescription drugs from strict liability for injuries caused by their products. Earlier California cases which addressed the applicability of comment K to prescription drug cases have required that the drug at issue be found to be "unavoidably dangerous." The *Brown* decision, however, disavowed this requirement and concluded that the comment K exception was intended to apply to all prescription drugs, not merely those which have been found to be "unavoidably dangerous." *Id.* at 482. In reaching this conclusion, the *Brown* court articulated numerous policy justifications for exempting such manufacturers from strict liability, particularly the importance of developing pharmaceutical products designed to alleviate pain and suffering. In light of these overriding public policy concerns, the *Brown* court concluded that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known

or reasonably scientifically knowable at the time of distribution." *Id.* at 482-83.

[12] Dow contends that under California law the exception for prescription drugs extends to the implants placed in Hopkins' body. It relies on a California Court of Appeal case that extends this exception to implant medical devices. *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377 (Ct. App. 1992). We need not consider whether this extension of the exception would be adopted by the California Supreme Court because we conclude the exception is inapplicable to the facts of this case.

[13] In the present case, the jury returned special verdicts, finding (1) that the mammary implant was defectively designed, (2) that it was defectively manufactured, and (3) that Dow failed to warn of a known or knowable risk of harm of the type the plaintiff alleged occurred to her. These findings were adequately supported by substantial evidence. Because of these jury findings, it is clear that the requirements for the exemption to strict liability announced in *Brown* for prescription drugs were not met. There was a failure to establish that the product was properly prepared or that the appropriate warnings were given. Thus, even if this prescription drug exemption were extended to implanted medical devices, the exemption would be inapplicable because the essential conditions of the special exemption were not met.

Because there was adequate evidence to sustain the jury's finding of liability on the basis of strict liability, we need not consider the other theories of liability.

V. THE DAMAGE AWARD

Hopkins was awarded $840,000 in compensatory damages and $6.5 million in punitive damages. Dow challenges the size of these awards. Dow contends that the compensatory damage award vastly exceeds actual damages sustained and further contends that the punitive damages award cannot be sustained because it is "grossly excessive," and no understandable relationship exists between actual damages and punitive damages. Hopkins asserts that the record contains ample evidence to support the amount of both the compensatory and the punitive damage awards.

A. *Compensatory Damages*

The record indicates that expert testimony presented at trial supported a finding that plaintiff had lost $404,083 in earnings as a result of her autoimmune disease. Her past medical bills were stipulated to be $37,318 and her future medical bills were computed to a present value of $31,600. Therefore, Hopkins' out-of-pocket losses amounted to $473,001. In addition, the jury apparently awarded Hopkins $366,999 in damages for "severe shock to the mental system" and mental pain. Other than a generalized allegation that Hopkins could not have suffered this degree of loss based on her claims, Dow offers no evidence to support its contention that the damages award was excessive. We conclude that the award of compensatory damages was proper.

B. *Punitive Damages*

"In reviewing an award of punitive damages, the role of the district court is to determine whether the jury's verdict is within the confines set by state law, and to determine, by reference to federal standards developed under Rule 59, whether a new trial or remittitur should be ordered. The court of appeals should then review the district court's determination under an abuse-of-discretion standard." *Browning-Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257, 279 (1989); *see also Bouman v. Block*, 940 F.2d 1211, 1234 (9th Cir.), *cert. denied*, 112 S. Ct. 640 (1991) (trial court has discretion to award punitive damages); *Kennedy v. Los Angeles Police Dept.*, 901 F.2d 702, 707 n.3 (9th Cir. 1989) (jury has considerable discretion to award punitive damages, and its award, if supportable, will not be lightly disturbed).

The Supreme Court stated that the following considerations are relevant to a determination of whether a punitive damages award is excessive or inadequate.

> (a) whether there is a reasonable relationship between the punitive damages award and the harm likely to result from the defendant's conduct as well as the harm that actually has occurred; (b) the degree of reprehensibility of the defendant's conduct, the duration of that conduct, the defendant's awareness, any concealment, and the existence and frequency of similar past conduct; (c) the profitability to the defendant of the wrongful conduct and the desirability of removing that profit and of having the defendant also sustain a loss; (d) the "financial position" of the defendant; (e) all the costs of litigation; (f) the imposition of criminal

> sanctions on the defendant for its conduct, these to be taken in mitigation; and (g) the existence of other civil awards against the defendant for the same conduct, these also to be taken in mitigation.

Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 21-22 (1991). Application of these standards in *Haslip* imposed a sufficiently definite and meaningful constraint on the discretion of fact-finders in awarding punitive damages. *Id.*

The Supreme Court recently provided additional guidance on the issue of excessiveness of punitive damages awards in *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711 (1993) (plurality). In upholding a judgment of $19,000 in actual damages and $10 million in punitive damages, the Court opined that punitive damages awards are "the product of numerous, and sometimes intangible, factors; a jury imposing a punitive damages award must make a qualitative assessment based on a host of facts and circumstances unique to the particular case before it." *Id.* at 2720. The Supreme Court identified various principles that may be considered when reviewing a punitive damages award. For instance, a court is not limited to considering the proportionality of the punitive award to actual damages sustained, but may also consider the magnitude of the harm that potentially could have occurred and the potential gain to the defendant. The Court noted that punitive damages had been awarded by an impartial jury, as a result of collective deliberations based on arguments of adversaries and evidence, and then reviewed by the trial judge and upheld by the unanimous decision of the State Supreme Court of Appeals, "is entitled to a strong presumption of validity."

Id. at 2719-20. Under these circumstances, the judgment of the Court declined to adopt a bright line test for evaluating the constitutionality of punitive damages awards and reiterated its position in *Haslip* that a "general concer[n] of reasonableness . . . properly enter[s] into the constitutional calculus." *Id.* at 2720 (citing *Haslip*, 499 U.S. at 18). The Court indicated that while proportionality to actual damages sustained is relevant in the analysis, it is the only one of several factors to be considered. *Id.* at 2722.

[14] The evidence presented at trial established that a large number of Dow silicone gel breast implants had been implanted in thousands of women. Each of these women was at risk of encountering the same fate from which Hopkins suffered. Therefore, Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, may properly be considered in imposing an award of punitive damages. Moreover, given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified. Coupled with the facts that Dow is a wealthy corporation and that Dow made a considerable amount of money from the sale of its implants, the jury's award of $6.5 million is reasonable in light of *TXO* and *Haslip*. Therefore, we conclude that Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award.

VI. CONCLUSION

We conclude that the district court properly granted Hopkins' motion for summary judgment on the statute of limitations question. We further conclude that the district court properly admitted expert testimony regarding the cause of plaintiff's injuries and the award of damages is therefore upheld.

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MARIANN HOPKINS, Plaintiff, v. DOW CORNING, Defendant.	NO. C 88 4703 TEH (JSB) ORDER DENYING DEFENDANT'S MOTION FOR NEW TRIAL OR, IN THE ALTERNATIVE, FOR JUDGMENT NOTWITHSTANDING THE VERDICT

This matter comes before the Court on defendant's motion for a new trial or, in the alternative, for judgment notwithstanding the verdict. Oral argument was heard in this matter on April 27, 1992. Frank Woodside and Jack McGowan appeared for defendant. Charles Louderback and Dan Bolton appeared for plaintiff.

BACKGROUND

This is a personal injury case brought by plaintiff Mariann Hopkins seeking recovery for injuries she received from defective Dow silicone breast implants. We held a nine week (bifurcated) jury trial in this case which culminated on December 13, 1991 when the jury found for Ms. Hopkins on all counts and awarded her $7.3 million in compensatory and punitive damages.

Defendant Dow Corning Corporation now moves for judgment notwithstanding the verdict, or in the alternative, for a new trial. These motions are based on five separate grounds. We issued rulings from the bench denying these motions in the April 27, 1992 hearing. This order is to memorialize those rulings.

DISCUSSION

A. FRCP Rule 59(b)

Dow Corning argues that it is entitled to a new trial under FRCP Rule 59(b) because the jury's verdict on causation was against the clear weight of the evidence and was the result of conjecture, confusion and sympathy.

We ruled on this issue during the course of the trial. After reviewing defendant's arguments at this juncture, we remain convinced that they are without merit. The jury found that there was causation between the silicone breast implants and the harm suffered by Ms. Hopkins. A review of the trial record indicates that there was more than enough evidence introduced to support this finding. This evidence was provided by three witnesses: Dr. Marc Lappe, Dr. Nir Kossovsky, and Dr. Frank Vasey. Each stated in unequivocal terms that it was his expert opinion that Ms. Hopkins' MCTD was the result of the silicone in her system.

On the basis of the evidence presented by both the plaintiff and the defendant in this case, we find that there was sufficient evidence for the jury to find for plaintiff on the issue of causation. Accordingly, defendant's motion for new trial is **DENIED.**

B. Inconsistency with Our Jan. 5, 1990 Order

Defendant argues that we erred in "admitting, over defendant's objection, evidence which was factually inconsistent with the fact determined by the Court's partial summary judgment order on the statute of limitations and legally inconsistent with the premises of that order."

In 1989, we entertained, from both parties, motions for summary judgment on the question of the statute of limitations. In an order dated Jan. 5, 1990, we granted plaintiff's motion, implicitly denying that of defendant.

Defendant argues that our order granting plaintiff's motion for summary judgment was based on 4 factual suppositions:

1. The *only* injuries for which plaintiff sought recovery were injuries derived from her Mixed Connective Tissue Disease (MCTD).

2. That, as a consequence of "Supposition 1, the only "discovery" which could trigger the running of the statute of limitations on any claim was discovery of the alleged relationship between the implants and the MCTD."

3. That defendant made no disclosure to plaintiff or her doctor of any information concerning reports of association between the breast implants and immunological sensitization or hyperimmune system response, such that plaintiff was unable to discover this association until less than a year before she sued.

4. That plaintiff believed the analysis that Dow Corning made of the implants which were removed from her

person in February 1986, which analysis reported discovery of no manufacturing defect in such implants, notwithstanding the fact that they ruptured.

Defendant argues that we accepted each of these suppositions as uncontroverted in deciding the summary judgment motion and that these same suppositions must bind plaintiff at trial.

Defendant misreads our Jan. 5, 1990 order. The critical point of that order is that Ms. Hopkins' action was not barred by the statute of limitations. We did not limit the injuries for which she could obtain recovery as defendant now contends. In her original complaint, plaintiff sought recovery for all actionable injuries which resulted from the defective breast implants. Defendant, here, tries to attribute positions to plaintiff which were not taken at the time that the summary judgment motion was decided.

We find no discrepancy between the positions taken by plaintiff in her statute of limitations order and her subsequent positions at trial. Therefore, defendant's motion for a new trial on this basis is **DENIED**.

C. Special Verdict Form

During the trial, defendant objected to the special verdict form submitted to the jury. We overruled the objection after careful consideration. Defendant now argues that we erred in overruling its objection to the failure of the special verdict slip to specify the jury's unanimous findings regarding the particular injuries for which defendant was held liable. Defendant asks us to grant a new trial on that basis.

Defendant's argument is that the verdict form that we submitted did not permit the jury to distinguish between the various injuries that the plaintiff alleged. In other words, the jury spoke on whether the silicone caused the plaintiff's injuries, but was not able to say, "the silicone caused Ms. Hopkins' MCTD, but not her ulcer." The verdict form limited the jury to finding causation for all of plaintiff's injuries, or for none of them.

The standard by which to measure the adequacy of a special verdict form is whether the questions asked are "adequate to obtain a jury determination of the factual issues essential to the judgment." *In re: Hawaii Federal Asbestos Cases*, 871 F.2d 891, 894 (9th Cir. 1991).

This was a bifurcated trial. In the liability phase, the issues essential to the judgment were whether the defendant acted in a tortious manner, and if so, whether this tortious conduct resulted in damage to the plaintiff. The exact kind and extent of the damages is to be determined during the damages section of the trial. Here, the jury was allowed to answer the operative question, did Dow's conduct result in sufficient damage to the plaintiff to establish *liability*. The jury answered that question affirmatively.

The special verdict form submitted in this case was adequate. For this reason, this motion for a new trial is **DENIED**.

D. Fraud Claim Re: 1986 Implants

Defendant argues that we committed error in submitting to the jury, plaintiff's claim of fraud with respect to the 1986 implants which were removed in 1991. Defendant presented the same question in a motion *in limine*. That motion was denied.

Defendant's argument is based on the fact that the implants which were implanted in 1986 and removed in 1991 were not found to be defective. Defendant contends that the trial produced no evidence of fraud with respect to the 1986 inserts and, alternatively, that we committed error in admitting any evidence regarding these inserts since they had not ruptured. According to defendant, we also committed error in that we allowed the plaintiff to argue to the jury her case of fraud with respect to these 1986 inserts.

Under the principles of California law, as articulated in *Kahn v. Shiley, Inc.* 217 Cal. App. 3d 848 (1990), a plaintiff may prove fraud with respect to a medical device, even where that device does not malfunction. In order to prove such a claim, a plaintiff must show that a manufacturer concealed material product information from potential users.

We find that in this case, plaintiff produced sufficient evidence that defendant concealed material product information to submit the question to the jury for determination. This being the case, defendant's motion for a new trial because we erred in submitting to the jury, plaintiff's claim of fraud with respect to the 1986 implants which were removed in 1991 is **DENIED**.

E. Punitive Damages

Defendant argues that the court erred in submitting to the jury, plaintiff's claim for punitive damages, or in the alternative, that the punitive damages that were awarded were excessive. Defendant asks us to enter judgment notwithstanding the verdict on this issue, or to grant a new trial unless plaintiff agrees to a remittitur.

Defendant's motion has two bases: Dow's prior exposure to an adverse punitive damages judgment and Dow's view that the damages awarded in this case were excessive. We have addressed the first of these bases several times in the past. At this point, we once again find that defendant's arguments regarding excessive punitive damage awards are unpersuasive. The second basis, the excessive amount of the punitive damages in this case is also uncompelling. The jury's verdict in this regard is well within the limits of reasonability given the findings that it made. For these reasons, defendant's motion for a directed verdict or for a new trial is **DENIED**.

CONCLUSION

After careful consideration and for the forgoing reasons, **IT IS HEREBY ORDERED** that defendant's motion for a new trial pursuant to FRCP Rule 59(b) is **DENIED**; defendant's motion for a new trial or for a directed verdict because the court erred in admitting evidence which was factually inconsistent with the fact determined by the court's partial summary judgment order on the statute of

limitations and legally inconsistent with the premises of that order is **DENIED**; defendant's motion for a new trial based on the inadequacy of the special verdict form used in this case is **DENIED**; defendant's motion for a new trial or for a directed verdict because the court erred in submitting to the jury plaintiff's fraud claim with respect to the 1986 implants is **DENIED**; and defendant's motion for directed verdict on the issue of punitive damages or, in the alternative, for a reduction in the punitive damages award is **DENIED**.

Good cause appearing,

IT IS SO ORDERED.

DATED: ___, 1992

THELTON E. HENDERSON,
CHIEF JUDGE
UNITED STATES
DISTRICT COURT

APPENDIX C

CHARLES M. LOUDERBACK
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Attorneys for Plaintiff
MARIANN HOPKINS

IN THE UNITED STATES DISTRICT
NORTHERN DISTRICT OF CALIFORNIA

* * *

MARIANN HOPKINS, Plaintiff, vs. DOW CORNING CORPORATION, Defendant.	CASE NO.: C 88 4703 TEH JUDGMENT

This action came on for trial before the Court and a jury, the Honorable Thelton E. Henderson, Chief Judge, Presiding, and the issues having been duly tried and the jury having rendered its verdict,

IT IS ORDERED AND ADJUDGED that the plaintiff MARIANN HOPKINS recover from the defendant DOW CORNING CORPORATION as and for compensatory damages the sum of Eight Hundred Forty Thousand Dollars ($840,000.00) and as and for punitive damages the sum of Six Million Five Hundred Thousand Dollars

($6,500,000.00), with interest on the above sums at the rate provided by law, and her costs of action.

Dated: January 09, 1992

Thelton E. Henderson,
Chief Judge
United States District Court

APPENDIX D

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MARIANN HOPKINS, Plaintiff-Appellee, v. DOW CORNING CORPORATION, Defendant-Appellant.	NO. 92-16132 D.C. No. CV-88-04703-TEH ORDER

Appeal from the United States District Court
for the Northern District of California

Before: LAY,* HUG, and SCHROEDER, Circuit Judges.

The panel, as constituted in the above case, has voted to deny appellant's petition for rehearing. Judge Hug and Judge Schroeder have voted to reject the suggestion for rehearing en banc, and Judge Lay has no recommendation for the suggestion for rehearing en banc.

The full court has been advised of the en banc suggestion and no active judge of the court has requested a vote on whether to rehear the matter en banc.

Fed. R. App. P. 35(b).

The petition for rehearing is **DENIED** and the suggestion for rehearing en banc is **REJECTED**.

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*Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.